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EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,780	EL-SHERBEINI ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-11,15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *4-11,15 and 17* is/are rejected.

7)☐ Claim(s) *4,7,9 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1,4-11, 15 and 17 are pending.
Claims 2-3, 12-14 and 16 have been canceled.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 19, 2004 has been entered.

Objections and Rejections Withdrawn

2. Claim 6 rejected under 35 USC 101, in light of claim 6 not having been amended to comprise the isolated and purified polynucleotide of claim 5, but must only be a host cell that comprises the polynucleotide of claim 5, which need not be heterologous or isolated and purified; the host cell of claim 6 uses claim 5 to define the nucleotide, but the hand of man is not evident in claimed host cell.

3. Claims 6 rejected under 35 USC 112, second paragraph for reciting the non-specific article "A and not reciting the phrase –isolated and purified--, because the claimed host cell reads on a native Pseudomonas aeruginosa cell or any cell that comprises any of the polynucleotides of claim 1.

4. Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2 and 3 depend from amended claim 1 and define the claimed polynucleotide to comprise "non-natural and modified nucleotides (claim 2) and non-natural linkages (claim 3). In light of the amendment of independent claim 1 to no longer recite paragraph (c) which provided for the presence of non-natural and modified nucleotides and non-natural linkages, claims 2 and 3 are no longer further limiting of claim 1, which has been amended and limited to a polynucleotide that encodes SEQ ID NO 2, a sequence that does not comprise non-natural, modified nucleotides or non-natural linkages; claims 2 and 3 are no longer further limiting of claim 1.

Objections and Rejections Maintained

5. The disclosure objected to because of the following informalities: The specification at pages 20-21 evidences blank lines; information is missing. No new matter should be submitted. Appropriate correction was not made, and therefore maintained.

6. Claim 4 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is maintained for reasons of record.

7. Claim 9 objected to because of the following informalities: Claim 9 in paragraph (a) recites the phrase "at least one host cell", which paragraph (b) recites the phrase "at least one of said cells"; both a singular and plural tense of the term "cell" are recited in the claim. The claim would be made clear through the amendment of paragraph (b) to recite –contacting said at least one cell -- to have the claim recite the same tense of the term "cell; is maintained for reasons of record.

8. Claims 4-7 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. Claims 4 and 10 rejected under 35 USC 112, second paragraph for reciting the phrase "the nucleotide sequence of SEQ ID NO 1"; this phrase lacks antecedent basis in independent claim form which they depend.

10. Claims 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 9-11 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

12. Claims 9-10 and 15 rejected under 35 USC 112, second paragraph for reciting the relative term "relative activity" still renders the claims indefinite, despite the fact that claims 9 and 15 have been amended to recite SEQ ID NO 2, as no point of reference for determining inhibitor activity is provided, as no reference level of MurC activity for the cells or polypeptide is determined prior to contacting the cell(s) or polypeptide with the candidate compound.

13. Claims 1, 4-6 rejected under 35 U.S.C. 102(b) as being anticipated by Eveland et al (1997), for reasons of record.

14. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by WO98/03533 (Oligos etc. and Oligos Therapeutics, Inc., January 29, 1998), for reasons of record.

15. Claims 1, 4-7 rejected under 35 U.S.C. 102(a or e) as being anticipated by SmithKline Beecham Corporation (EP0889123 A2), for reasons of record.

Response to Arguments

16. Applicant requested evidence that a polynucleotide molecule could function as an expression vector. US Pat. 6,734,013; US Pat. 6,716,813; US Pat. 6,635,249 and US Pat. 6,599,692 define the term expression vector to encompass naked DNA operatively linked to a promoter, which reads on isolated prokaryotic DNA (citations attached herewith).

17. Applicant in response to the objection to the specification for informalities, specifically pages 20-21 evidencing blank lines states that the information missing from pages 20-21 will be

provided upon receiving a notice of allowance. The objection is maintained as the blank lines still exist in the specification.

18. Claims 4 and 9 objected, to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim and for informalities, respectively, was not addressed and therefore maintained for reasons of record.

19. The rejection of claims 4-7 under 35 U.S.C. 112, first paragraph (written description, the basis of enablement), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is traversed on the grounds that "the claims have been amended generally to change said phrase the "having the amino acid sequence of SEQ ID NO :2".

20. It is the position of the examiner that the claims are directed to polynucleotide sequences encode polypeptides of any specific biological activity, the polypeptides are not required to evidence MurC biological activity. A polynucleotide that comprises the polynucleotide of claim 1(b) which is not directed to a polynucleotide that encodes a polypeptide and is not required to be a sequence of any specific size, but must only be a sequence that is complementary to the coding sequence of SEQ ID NO:2. The sequences of claim 1(b) may be any sequence of 2 or more nucleotides in length. The genus of polynucleotides that comprise the polynucleotide of claim 1(b) has not been described, what has not been described has not been enabled; only a scope of what is now claimed has been described in such a way that one of skill in the art would have realized that Applicant had possession of the invention at the time of filing.

21. Claim 4 is directed to a polynucleotide that comprises the nucleotide sequence of SEQ ID NO 1; a genus polynucleotide sequences which evidences sequences that are 5' and 3' to SEQ

ID NO 1 have not been described, and what is now claimed does not encode a polypeptide of any specific sequence, no less a Pseudomonas aeruginosa MurC polypeptide with MurC activity.

22. Claim 5 is directed to a genus of polynucleotides that do not encode a polypeptide of any specific sequence or biological function or activity nor is the polynucleotide claimed to have been derived from any specific source. The polynucleotide of claim 5 comprises any polynucleotide of claim 1, the size and sequence that the claimed polynucleotide comprises is unclear, and the genus of polynucleotides that comprise any portion of the polynucleotide of claim 1 has not been described.

23. Claim 6 is directed to a host cell that comprises the polynucleotide of claim 5; in view of the fact that the genus of polynucleotides of claim 5 evidence original descriptive support, the genus of host cells also has not been described.

24. Claim 7 which is directed to a genus of processes for expressing a MurC protein of Pseudomonas aeruginosa have not been described, in light of the fact that claim 5, is not directed to a genus of isolated polynucleotides that encode Pseudomonas aeruginosa MurC polypeptides; the polynucleotides of claim 5 are not required to encode a polypeptide of any specific biological function or activity, nor to comprise any specific consensus or conserved sequence that conveys Pseudomonas aeruginosa MurC activity. In view of the fact that the vector and host cell do not encode a genus of MurC proteins, the genus of processes for expressing a genus of MurC proteins of Pseudomonas aeruginosa have not been described. In light of the fact that written description is the basis for enablement, the instant specification not evidencing original descriptive support for the full scope of what is now claimed, the instantly

claimed process is also not enabled for the full scope of the claims. The rejection is maintained for reasons of record.

25. The rejection of claims 4 and 10 under 35 USC 112, second paragraph for reciting the phrase "the nucleotide sequence of SEQ ID NO 1"; the phrase lacking antecedent basis in independent claim form which they depend, is traversed on the grounds that SEQ ID NO 1 encodes SEQ ID NO 2.

26. It is the position of the examiner that SEQ ID NO 1 is directed to a polynucleotide that is larger than the polynucleotide that encodes SEQ ID NO 2. The polynucleotides of claim 1, are recite with closed language "consisting of", and the polynucleotide of claims 4 and 10 are claimed "comprising" SEQ ID NO 1. Both claims 4 and 10 are not limited to the coding region of SEQ ID NO 1 that encodes SEQ Id NO 2. SEQ ID NO 1 is 58 nucleotides larger than SEQ ID NO 2. The independent claim should recite SEQ ID NO 1, and SEQ ID NO 2 in the alternative, then depend claims 4 and 10 would be further limiting through the recitation of SEQ ID NO 1, and SEQ ID No 1 would evidence antecedent basis in the independent claim.

27. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is not addressed and therefore maintained for reasons of record.

28. The rejection of claims 9-11 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is not addressed, and therefore maintained for reasons of record. See MPEP § 2172.01.

29. The rejection of claims 9-10 and 15 under 35 USC 112, second paragraph for reciting the relative term "relative activity" is traversed on the ground that "Applicant reminds the Examiner

that he is free to be his own lexicographer and need not use the Examiner's preferred phasing" and running a control is common practice.

30. It is the position of the examiner that activity of the MurC protein is not determined relative to anything. No comparison can be made to determine a relative activity, as no point for determining any other activity has been set forth in the claims. The activity of the candidate compound has not been defined. The activity of the MurC polypeptide was not determined prior to contacting the candidate compound, therefore, inhibition of activity cannot be determined.

The issue raised by the examiner is not lexicography, but "relative activity". In order to determine a relative activity, the activity must be compared relative to something else. No comparison step is recited in the claims, nor is the utilization of a control recited. The specification teaches a critical comparison step for determining relative activity, which is not claimed. The rejection is maintained for reasons of record.

31. The rejection of claims 1 ,4-6 under 35 U.S.C. 102(b) as being anticipated by Eveland et al (1997), is traversed on the grounds that the claims have been amended, thus obviating the rejection.

32. It is the position of the examiner that Eveland et al still anticipate the instantly claimed invention as Eveland et al discloses a polynucleotide complementary to the coding sequence of SEQ ID NO, and comprises a conserved consensus sequence of MurC protein/polypeptides. The polynucleotide of claim 1(b) includes within its scope sequences that encode the conserved MurC polypeptide consensus sequence. The rejection is maintained for reasons of record.

33. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by WO98/03533 (Oligos etc. and Oligos Therapeutics, Inc., January 29, 1998), is traversed on the grounds that the claims have been amended.

34. It is the position of the examiner that claims 1(b) and claims that depend therefrom still read on the applied prior art.

35. The rejection of claims 1, 4-7 under 35 U.S.C. 102(a or e) as being anticipated by SmithKline Beecham Corporation (EP0889123 A2) is traversed on the grounds that the claims have been amended.

36. It is the position of the examiner that claims 1(b) and claims that depend therefrom still read on the applied prior art.

New Combination of Claim Limitations/New Grounds of Rejection
Allowable Subject Matter

37. Claim 8 is rejected under 35 USC 112, second paragraph (see rejection below), but contains subject matter that defines over the prior art of record.

38. Claim 17 is rejected under 35 USC 112, second paragraph and is dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Objections

39. Claims 4,7 and 10 are objected to because of the following informalities:

40. Claims 4 and 10 recite the term "nucleotide sequence"; the specification defines the term "nucleotide" to be representative of a single nucleic acid. Claims 4 and 10 broaden the scope of the independent claims which are directed to a polynucleotide; claims 4 and 10 include within the scope of the claims a single nucleotide (nucleic acid molecule).

41. Claim 7 recites the phrase "in conditions under which allow"; something is missing, or the word order should be modified, or one too many words are recited.----in and under conditions which allow---

42. Appropriate correction is required.

Claim Rejections - 35 USC § 112

43. Claim 4-5, 7-11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 10 recite the term "nucleotide" which is not the same term as polynucleotide recited in the independent claims. How is the nucleotide that is SEQ ID NO 1 different from the recited polynucleotide of the preamble of the claim? The term "nucleotide" lacks antecedent basis in claim 4 and claim 1 from which it depends. What is the difference in structure between the two recited molecules?

Claim 5 recites the phrase "a polynucleotide of claim 1"; the term "a" is an indefinite article. The claim should recite -----the--- polynucleotide of claim 1.

Claim 7 recites the phrase "an expression vector of claim 5"; the term "an" is an indefinite article. The claim should recite -----the ---- expression vector of claim 5.

Claim 7 recites the term "protein" and depends from claims 5 and 1, respectively which recite the term polypeptide. How do the polypeptide of claim 1 and the protein of claim 7 differ one from the other or the same as each other ? Are the two different terms intended to claim differing molecules? How are the two molecules the same or different from each other? While

the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 8 recites the phrase "having the amino acid of SEQ ID NO 2", but SEQ ID NO 2 comprises a plurality of amino acids set forth in a sequence, which amino acid is being claimed is unclear as the SEQ ID NO is representative of a sequence and not a single amino acid. Amendment of claim 8 to recite the term ----sequence---- following the phrase "amino acid" could obviate this rejection

Claim 9 paragraph (a) recites the phrase "at least one host cell" which defines a genus that contains one or more cells. Paragraph (b) of claim 9 recites "at least one of said cells", which refer back only to a plurality of cells, thus excluding the embodiment that includes a single cell. Claim 9 paragraph (b) should recite: ------contacting said at least one host cell---- to include the species of invention directed to only a single cell defined to be within the scope of the invention in paragraph (a). The claim is silent with respect to the expression of the encoded polypeptide. Does the expression vector express the MurC polypeptide?

Claim 10 recites the phrase "the polynucleotide has the nucleotide sequence of SEQ ID NO 1"; why is SEQ ID NO 1 not considered to be a polynucleotide when it has over a 1000 nucleic acids in the sequence? What is the difference between the recited polynucleotide and the nucleotide of the claim? Why aren't the same terms used to refer the claimed composition ? How do the nucleotide and polynucleotide structurally differ one from the other? While the specification can be used to provide definitive support, the claims are not read in a vacuum.

Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 11 recites the phrase "at least one cell" and depends from claim 9 which recites the phrase "at least one host cell (paragraph 9(a))" and "at least one of said cells (paragraph 9(b))". It is not clear that the cell of claim 11 is the host cell of claim 9 because the cell of claim 11 does not refer back to "said host cell". What cells are being used to compare the activity of MurC before and after contact with a candidate compound?

Claims 11 and 17 recite the phase "is determined"; the claim should recite positive, active voice methods steps or modify one of the already recited active voice methods steps. ---wherein the determining of relative activity comprises the steps of measuring and comparing----- or an equivalent active voice methods step.

Claim Rejections - 35 USC § 102

44. Claims 1, and 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Black et al (US Pat. 6,310,193; effectively filing date September 30, 1997.

Please Note: The following art rejection is being made in light of the polynucleotide of claim 1 (b), need only comprise a portion of the nucleic acid of 1(a), and must encode a MurC protein.

Black et al disclose the instantly claimed invention directed to a purified and isolated polynucleotide, that is complimentary to SEQ ID NO 2, over any length of SEQ ID NO 2, and may comprise additional nucleic acids, and encode a MurC polypeptide (see title, and Table 2, col. 22, lines 25-33; SEQ ID No 2, cols 33-34, amino acids 108-110, 112-115, 117-118 of SEQ

ID NO 2 of Black are identical to the conserved amino acids of Applicant's SEQ ID NO 2, positions 127-129, 131-134 and 136-137 respectively. The polynucleotide therefore encodes and comprises a polynucleotide sequence that is complementary to the non-coding strand of the polynucleotide that encodes SEQ ID NO 2 and the translated polypeptide is a MurC polypeptide (see Black et al, title).

The isolated and purified polynucleotide was cloned into a vector (see col. 21, lines 5-25) and inserted into a recombinant cell (see col. 20, lines 51-64; col. 21, lines 20, and lines 26-31).

The recombinant host cell that comprised the polynucleotide encoding a MurC polypeptide was cultured, host cell expressed the encoded the recombinant MurC polypeptide which was subsequently recovered and purified (see col. 21, lines 32-43). See all claims of Black et al. The reference anticipates the instantly claimed invention of claims 1(paragraph (b), and claims 5-7 which are dependent from claim 1(paragraph (b)).

45. Claims 1, 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith (PG Pub US 2004/0052799, effective filing date December 17, 1997 (sequences from H.pylori strain J99 (see page 132, paragraph [0410]) as evidenced by the sequences in Swiss Prot for MurC , strain J99 (Q9ZLL2), disclosed in '799 as SEQ ID NO 2845 (polynucleotide) and SEQ ID NO 7607, amino acid sequence for polypeptide (see claims 182 and 188, MurC sequences and Table 1, page 101, col. 2, open reading frame termed: "09ce52017_25890837".)

Smith et al disclose an isolated polynucleotide, SEQ ID NO2845, that encodes a MurC polypeptide, which was cloned (see page 117, paragraph [0247]) and expressed (see page 119, [0278] through paragraph [0287]) as a polypeptide (see page 121, paragraphs [0291]through

[0294]) of SEQ ID NO 7607, the polypeptide having been isolated and purified (see claims 182 and 188). The polynucleotide encodes a sequence that is complementary to the non-coding sequence of SEQ ID NO 2, and therefore comprises a polynucleotide of instant claim 1(paragraph b); specifically see conserved encoded amino acid positions that correspond to positions 51-53 ("GSD"), positions 63-64 ("LG"), positions 127, 131-133, and 137 ("G-HGK---T ") and positions 177-182, 184-186 of Instant SEQ ID NO 2 ('EADESD-SFL"), as evidenced by the sequence disclosed for J99 MurC (Swiss-Prot protein number Q9ZLL2).

The reference also discloses antisense polynucleotides of the disclosed coding polynucleotide sequences.

The reference anticipates the instantly claimed invention directed to an isolated polynucleotide that encodes a MurC polypeptide that comprises a nucleotide sequence that is complementary to the polynucleotide sequence that encodes SEQ ID NO 2 and comprises a polynucleotide sequence that encodes a polypeptide with an amino acid sequence taken from SEQ ID NO 2.

Conclusion

46. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

47. Yuan et al US 2002/0015678A1 (effective filing date Feb. 10, 1998) is cited to show a method of screening for MurC inhibitors (see all claims).

48.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two-week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

June 21, 2004

L. F. Smith

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